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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,185	06/17/2002	Pascual Perez	34934-PCT-USA 072667.0180	2915
21003	7590	09/23/2005	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			ROBINSON, KEITH O NEAL	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/048,185

Applicant(s)

PEREZ ET AL.

Examiner

Keith O. Robinson, Ph.D.

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-8, 10, 12, 14, 15, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-8, 10, 12, 14, 15, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 June 2005 has been entered.

2. Claims 1-3, 5-8, 10, 12, 14-15 and new claims 18-19 are pending in the application and claims 4, 9, 11, 13, 16 and 17 have been canceled without prejudice.

3. The text of those sections to Title 35, U.S. Code not included in this action can be found in a prior Office Action, filed 25 June 2004.

New Claim Rejections - 35 USC § 112, second paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Step (c) does not state which "parental maize line" is the recurrent parent.

This rejection can be overcome by the insertion of - - of interest - - after "line" in step (c).

Response to Arguments

Claim Rejections - 35 USC § 112, first paragraph - Enablement

6. Claims 1-3, 5-8, 10, 12, 14-15 remain rejected and new claims 18-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the Office Action filed 25 June 2004, pages 3-9 as applied to claims 1-12 and 14-16.

Applicant argues that the instant invention is broadly applicable to different maize lines based on the documented ability of others to utilize several maize lines in generating hybrid lines when combined with A188 or Hi-II as the other parent (see pages 7-8, last and first paragraphs, respectively, of the REMARKS, filed 23 June 2005).

This is not persuasive. Though the listed references document lines that may be used to generate hybrids, the instant specification fails to produce such a list. Thus, there is no evidence that other lines can be used in the invention as claimed. Even if

one of skill in the art were use the lines as listed in the references listed on pages 7-8 of the REMARKS filed 23 June 2005, this list of maize lines does not encompass the broad genus of "different maize lines". Furthermore, the claims are not limited to hybrids which have either A188 or Hi-II as one parent.

Applicant argues that transformation of several plant species has been achieved by utilization of T-DNA vectors (see page 8, second paragraph of the REMARKS filed 23 June 2005).

This is not persuasive. The specification does not provide any evidence of any plants, except maize, used in the invention as claimed. Applicant states "several plant species [have] been achieved by utilization of T-DNA vectors"; however, this does not enable Applicant's invention to work with "all the claimed groups of plants including crop plants, vegetables, and flowers...as amenable targets for *Agrobacterium*-mediated gene transfer" as stated on page 8 of the REMARKS filed 23 June 2005. The declaration of Dr. Perez that "making hybrids...are well known in the art" does not enable the invention to be used with any hybrid formed by any cross between any line of interest and any line adapted to transformation. As stated above, the specification only provides evidence of the invention being used with maize. Furthermore, the suggested plant species of sunflower, canola, tomato or melon are not "recalcitrant or unsuited to transmission", as newly claimed.

Applicant argues that methods for analyzing and comparing genomes are well known in the art (see page 9 of the 'REMARKS', second paragraph).

This is not persuasive. The Examiner agrees that methods for analyzing and comparing genomes are well known in the art; however, the art also shows that such methods are unpredictable, as discussed previously (see page 8, first and second paragraphs of the Office Action filed 25 June 2004). In addition, Applicant only discloses the use of RFLP with maize and has not shown that all methods for analyzing and comparing genomes of transformed plants will work with the invention as claimed. The Examiner maintains the rejection of this previous Office Action (see page 4, first paragraph of the Office Action, filed 21 January 2005).

Applicant's arguments regarding new claims 18 and 19 in that they are limited to maize, thus overcoming the Examiner's previous rejections are not persuasive (see page 9, first paragraph).

Though the claims are limited to maize as the "maize line suited to transformation", they are not limited to A188 or Hi-II as the "maize line suited to transformation".

Applicant argues that Welsh et al demonstrate that the Examiner's rejection is "unsound" (see page 10, third paragraph of the REMARKS filed 23 June 2005).

This is not persuasive. Applicant has failed to provide any evidence showing that the Examiner's reliance upon Welsh et al is not sound and therefore this is merely an

opinion that is not supported by fact nor evidence. Applicant is reminded that Welsh et al was cited to demonstrate the unpredictability inherent in identifying genomic sequences in the absence of a recitation of highly stringent conditions.

Applicant's arguments with regards to the number of backcrosses used in the invention have been considered and are not persuasive (see the Perez declaration, 23 June 2005, paragraphs 12 and 13).

The Examiner maintains the rejections of record set forth in the previous Office Action filed 25 June 2004, page 7, second paragraph. In summary, it was stated that it is impossible to obtain truly isotransgenic lines if the transgene were originally inserted into the non-agronomic parent.

Claim Rejections - 35 USC § 112, first paragraph – Written Description

7. Claims 1-3, 5-8, 10, 12, 14-15 remain rejected and new claims 18-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office Action filed 25 June 2004, pages 10-12 as applied to claims 1-12 and 14-16.

Applicant argues that the Examiner appears to be basing the written description rejections on a lack of working examples of certain embodiments of the invention.

This is not persuasive. The Examiner is not basing the written description rejections on a lack of working examples of certain embodiments of the invention. The Examiner has explained the reasons for the written description rejections in a previous Office Action (see pages 10-12 of the Office Action filed 25 June 2004), namely that the single exemplified species of transformed maize plants with A188 as one parent, is not representative of the broadly claimed genus of any plant species, or the broadly claimed genus of any maize genotype.

Applicant argues that the Examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize Applicant's invention.

This is not persuasive. The Examiner has already met this burden and has presented reasons why persons skilled in the art would not recognize Applicant's invention (see pages 10-12 of the Office Action filed 25 June 2004). In summary, the reasons include lack of written description regarding the genetic or morphological description of the lines used in the invention or the markers used in the invention.

Claim Rejections - 35 USC § 102

8. Claim 12 remains rejected and new claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Ragot et al as stated on pages 14-15 of the previous Office Action, filed 25 June 2004, for claims 11-12 and 16.

Applicant argues, "theoretical assumptions cannot ground a rejection based on anticipation" (see page 12, second paragraph of REMARKS filed 23 June 2005).

This is not persuasive. The Examiner has explained in a previous Office Action why the claims are anticipated by Ragot et al (see pages 14-15 of the Office Action filed 25 June 2004). In short, the Examiner refers Applicant to *In re Thorpe*, which teaches that a product-by-process claim may be properly rejectable over the prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. In the instant application, the isotransgenic corn plants taught by Ragot et al differ from the claimed corn plants only in their method of making (see page 14, third and fourth paragraphs, of the Office Action filed 25 June 2004).

In addition, the Examiner refers Applicant to *In re Best*, which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. Applicant has failed to provide any evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Applicant argues that the amendment of claim 12 overcomes the previous rejections (see page 13, last paragraph of the 'REMARKS' filed 23 June 2005).

This is not persuasive. Though the claim has been amended to include recalcitrant or unsuited to transformation lines, Ragot et al teach recalcitrant or unsuited to transformation lines, i.e. elite inbred corn lines (see page 46, fourth paragraph).

With regards to Applicant's reference to the Perez declaration regarding backcrossing, the Perez declaration provides a theoretical scenario, and there is no indication that linkage drag occurred in the plants of the Ragot et al reference. In addition, the Perez declaration admits that 3 or 4 backcrosses, as taught by Ragot et al, would be sufficient to obtain isotransgenic lines (see page 6, lines 1-3).

Claim Rejections - 35 USC § 103

9. Claims 1-3, 5-8, 10, 12, and 14-15 remain rejected and new claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishida et al, in view of Does et al, Hie et al, Armstrong et al, and Ragot et al as stated on pages 15-18 of the previous Office Action, filed 25 June 2004, for claims 1-12 and 14-16.

Applicant argues that the selection step in claim 1 is absent and not suggested by the prior art and thus the claims are not obvious in view of the cited art (see page 14, third paragraph of the REMARKS filed 23 June 2005).

This is not persuasive. The Examiner has addressed this argument in a previous Office Action wherein, in summary, it was stated that the test for obviousness is what

the combined teachings of the references would have suggested to those of ordinary skill in the art (see page 11, first paragraph of the Office Action filed 21 January 2005).

The Perez declaration does not overcome the 103 rejection set forth in the previous Office Action. The figures in the Perez declaration as well as the argument with regard to backcrossing seem to address the Ragot et al reference; however, the basis of the 103 rejection is the combination of references not a single reference.

Applicant argues that the Examiner has improperly used Applicant's teachings as a blueprint to reconstruct the claimed invention from disparate references that contain no motivation to combine their disclosures.

This is not persuasive. The Examiner simply quoted from Applicant's specification to show that the references used in the 103 rejection used parental plants and process steps which were inherently the same as those instantly claimed. Further, the Examiner disagrees with Applicant in the assertion that there was no motivation to combine the references. The Examiner directs Applicant's attention to page 17, last paragraph, last two sentences of the Office Action filed 25 June 2004 where it states the motivation (i.e. desirability of isogenic transgenic lines and success in obtaining them as taught by Ragot et al).

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keith O. Robinson, Ph.D.

September 8, 2005

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

